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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 493813 NJC	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. <b>PCT/NZ2003/000269</b>	International Filing Date (day/month/year) 5 December 2003	Priority Date (day/month/year) 6 December 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. <sup>7</sup> A61M 16/00		
Applicant FISHER & PAYKEL HEALTHCARE LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.  
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 29 June 2004	Date of completion of the report 22 March 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  Sue Thomas Telephone No. (02) 6283 2454

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

Claims 1-42 are directed to a mouthpiece or system including mouthpiece for oral delivery of gases having gas passageway through mouthpiece and means to diffuse gases at the patient receiving end

Claims 43-49 are directed to a mouthpiece or system including mouthpiece for oral delivery of gases having gas passageway through mouthpiece and means to alter distance between a vestibular shield and an extra oral sealing means

Claims 50-55 are directed to a mouthpiece or system including mouthpiece for oral delivery of gases having gas passageway through mouthpiece and nose attachment connected to upper edge of an extra oral sealing means

Common feature of mouthpiece having gas passageway therethrough is not novel in light of WO 199003199.

No other feature which could provide novelty to the application as a whole is common to all claims.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 6-12, 14, 17-19, 21, 24, 26, 34-36, 38-55	YES
	Claims 1-5, 13, 15, 16, 20, 22, 23, 25, 27-33, 37, 56, 57	NO
Inventive step (IS)	Claims 10, 11, 14, 18, 19, 35, 36, 38-42, 44-46, 49	YES
	Claims 1-9, 12, 13, 15-17, 20-34, 37, 43, 47, 48, 50-57	NO
Industrial applicability (IA)	Claims 1-57	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

D1 US 4495945  
D2 US 2002/0069872  
D3 US 5590643  
D4 EP 1075848  
D5 DE 19944242  
D6 WO 1990003199  
D7 WO 1995014507  
D8 US 4895143  
D9 WO 1999058181  
D10 US 4098270

**NOVELTY (N) Claims 1-5, 13, 15, 16, 20, 22, 23, 25, 27-33, 37, 56, 57**

Claims 1-5, 13, 15, 16, 20, 22, 23, 25, 27-33, 56, 57 : All the features of each of these claims are disclosed in D1. For instance, for claim 1 as follows:

Vestibular shield overlaps user's teeth and gums

Figure 1

Gas passageway through vestibular shield and mouthpiece

Items 70, 72, 74

Extra oral sealing means associated with gas passageway

Figure 2

Gas diffusing means associated with passageway and inner surface of shield

Items 70, 72, 74

Similarly, the features of the other claims in this group are provided by D1.

Claim 37: In a similar manner, the features of claim 37 are provided by D5.

**INVENTIVE STEP (IS) Claims 1-9, 12, 13, 15-17, 20-34, 37, 43, 47, 48, 50-57**

Claims 1-5, 13, 15, 16, 20, 22, 23, 25, 27-33, 37, 56, 57 are not novel and consequently lack inventive step

Claims 1, 2, 12, 15, 16, 20, 27-30: All the features of these claims are provided when D6 and D7 are read together as would be considered obvious by a person skilled in the art.

Claims 7, 9 and 12: In a similar manner, the features of these claims are provided by D1 with D3.

Claims 21, 22, 23, 24: Similarly, the features of these claims are provided by D1 with D4.

Claims 21, 24, 26: Similarly, the features of these claims are provided by D1 with D2.

Claims 43, 47, 48: Similarly, the features of these claims are provided by D2 with D6 and by D6 with D7.

Claims 50, 51: Similarly, the features of these claims are provided by D6 with D7 or with D8 or with D10. For claim 50, D6 can also be read with D9.

Claims 52: Similarly, the features of claim 52 are provided by D6 with D8

Claims 53, 54: Similarly, the features of these claims are provided by D6 with D10

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

Claim 39 is not clear because there is no antecedent to "said tapered end" in claim 37 to which claim 39 is appended. In this opinion claim 39 has been read as appended to claim 38.

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of BOX V**

Claims 6, 8, 17, 34, 55: The features added by these claims such as gas inlet means for allowing connection of mouthpiece to gas supply, bellows, corrugations, or accordion-like pleats to contract or extend passageway, nose flap and nasal cannula to supply gas to nasal cavities, are well known in the art of respiration and do not add invention to the devices.